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In Search of Solidarity – Personalised Medicine in Denmark

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In Search of Solidarity

– Personalised Medicine in Denmark*

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ABSTRACT

I denne artikel evaluerer forfatteren, hvorvidt de juridiske rammer for udviklingen af personlig medicin i Danmark kan legitimeres som en form for solidaritet. Artiklen har fokus på de seneste ændringer af Sundhedsloven, der opretter Nationalt Genom Centre. Artiklen når frem til, at nogle bestemmelser i loven ikke er forankret i patientens selvbestemmelsesret, da biologisk materiale i nogle tilfælde kan opbevares og bruges til forskning uden informeret samtykke. For at evaluere hvorvidt denne praksis kan forklares som en form for solidaritet, gør forfatteren brug af Prainsack og Buyx beskrivelse af solidaritet, hvilken påstår, at solidaritet kræver gennemsigtighed, sandfærdighed og at patienter beskyttes mod negative konsekvenser.

Baseret på denne analyse argumenteres der for, at den nuværende lov ikke kan betragtes som en form for solidaritet, fordi patienterne ikke bliver tilstrækkelig informeret om, at formodet samtykke finder anvendelse i det danske sundhedsvæsen. Det findes også kritisabelt, at børn og voksne uden evne til at give samtykke er omfattede af modellen for formodet samtykke. Derfor anbefales det, at alle patienter bliver bedre informerede om, at biologisk materiale i nogle tilfælde kan opbevares og bruges til forskning og at børns rettigheder i forbindelse med omfattende genom-undersøgelse sættes i fokus.

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1. Introduction

> … We must recognize that not all medicine works on the individual patient. People with, for example, arthritis or cancer may find that they have to go through many different treatments or experience many side effects. There are also diseases which we do not know the cause of and which are therefore difficult to treat.
>
> It does not have to be this way in the future.
>
> With Personalised Medicine, we can develop new treatments through the use of knowledge and new technologies. Using genetic knowledge about the disease and the individual patient's characteristics, we can diagnose diseases better and target treatment to a greater extent…[1]

Inspired by discreet successes, a growing number of governments seek to advance personalised medicine through adopting political strategies designed to stimulate use of genetic data in healthcare.[2] Personalised medicine uses genomic data, combined with other forms of big data, to stratify patients and develop individualised treatments. The proposed benefits include saving lives and avoiding side effects, while reducing healthcare costs.[3] Through advances in genome sequencing, it is possible to identify whether an individual carries an increased risk of certain breast and colon cancers, or whether a patient can expect to benefit from specific cancer drugs. Using this knowledge, patients can, in some cases, avail of more effective, tailored prevention and treatment.[4] At the same time, the literature highlights several legal concerns, including, limitations of informed consent, misuse of data by third parties, genetic discrimination, privacy, incidental findings, confidentiality among genetic relatives, and equitable access to treatment.[5] This raises the question,

1 Sundheds-og Ældreministeriet, Personlig Medicin til Gavn for Patienterne: National Strategi for Personlig Medicin 2017–2020, Denmark, 2016, p. 3.

2 For a succinct overview of personalised medicine in Europe, see Nimmesgern, E., Benediktsson, I., & Norstedt, I., Personalized Medicine in Europe, Clinical and translational science, Vol. 10, Nr. 2, p. 61–63, 2017.

3 Dzau VJ, Ginsburg GS, Van Nuys K, Agus D, Goldman D, Aligning incentives to fulfil the promise of personalised medicine, Lancet. Vol. 385(9982), pp. 2118–9, 2015.

4 Hong K., Oh B., Overview of personalized medicine in the disease genomic era, BMB Rep. Vol. 43, Nr. 10, p. 643–8, 2010.

5 See, for example, Brothers, KB., Rothstein, MA., Ethical, legal and social implications of incorporating personalized medicine in healthcare, Per. Med. Vol 12, Nr. 1, pp. 43–51, 2015, p. 46; McClellan, K. A., Avard, D., Simard, J., & Knoppers, B. M.,

can governments promote access to patient data in the name of good population health, while simultaneously respecting patients' legal rights?

In the field of healthcare, law plays an important role in negotiating the balance between individual rights and collective interests. Law codifies rights, like respect for private life and protection of personal data, and provides for remedies where violations occur.[6] Law safeguards individual autonomy through requiring consent to treatment and sharing of confidential information.[7] Furthermore, legislation can protect patients from negative consequences of receiving treatment, such as discrimination based on genetics, as well as exclusion from access to healthcare. Yet, law also recognises the individual and collective as inevitably intertwined.[8] Indeed, the interests of the collective may sometimes outweigh the rights of the individual; for instance, protection of health is a legitimate aim under the European Convention on Human Rights.[9] The interplay between the collective and individual in law is ever shifting and challenged by developments in genomics.

Against this backdrop, this article investigates provisions of the Danish Health Act (*Sundhedsloven*), including recent amendments intended to support personalised medicine.[10] Denmark is selected as a case study as the government has begun to implement personalised medicine in mainstream healthcare, including adopting a national strategy and enacting legislation *inter alia* establishing a National Genome Centre.

Personalized medicine and access to health care: potential for inequitable access?. European journal of human genetics, Vol. 21, Nr. 2, pp. 143–147, 2013.

6 For example, European Union, Charter of Fundamental Rights of the European Union, 26 October 2012, 2012/C 326/02, Articles 7, 8, 47.

7 For example, Bekendtgørelse af sundhedsloven nr 1286, 2 November 2018, § 15, § 41.

8 Nedelsky argues that the idea of autonomy as in opposition to the collective is distorted. Instead, liberal rights should be transformed through a relational approach. Nedelsky, J. Law's Relations: A Relational Theory of Self, Autonomy, and Law, Oxford University Press. Oxford, 2011 p. 53, 73.

9 Council of Europe, European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14 ETS 5, 1950, Article 8.

10 For a thorough analysis of Danish law in the context of personalized medicine, see: Mette Hartlev & Katharina Ó Cathaoir, Lovgivning – realiteter og udfordringer in Personlig medicin – filosofiske og tværvidenskabelige perspektiver, (Eds.) Klausen, SH., & Christiansen, K. (Munksgaard Forlag, forthcoming).

I argue that, despite the Ministry of Health's claims to the contrary, self-determination is not the dominant ethical basis underlying selected provisions of the Health Act. Instead, the law pursues collective interests by permitting reuse of biological samples for research without patients' informed consent. In response, I evaluate whether the legislation could instead be reframed as an act of solidarity.

As solidarity has (justifiably) been criticised as vague and lacking a unifying theory, I rely on the work of Prainsack and Buyx, who define solidarity as:

> Enacted commitments to carry 'costs' (financial, social, emotional or otherwise) to assist others with whom a person or persons recognise similarity in a relevant respect.[11]

Prainsack and Buyx's model is chosen for its comprehensiveness (it is based on an extensive literature review) and for its proximity to the topic of this paper (the authors' model was designed for application in bioethics, specifically personalised medicine and health databases). While solidarity is frequently drawn upon in bioethics, no other approaches were found that offered the same transparency and traceability in terms of what solidarity in bioethics might require (see further section 3). Prainsack and Buyx further approach solidarity as an enacted practice (distinct from a normative idea or sentiment), which renders their approach well suited to an analysis of legislation.[12]

In evaluating the appropriateness of Danish legislation, I also draw on international legal norms codified in the European Convention on Human Rights, European Convention on Biomedicine and the Genetic Testing Protocol to the Biomedicine Convention, as well as non-binding recommendations and declarations.[13] To expose the intentions behind the

11 Prainsack B., Buyx, A., Solidarity in Biomedicine and Beyond. Cambridge University Press United Kingdom, 2017, p. 52.

12 Ibid., p. 45.

13 Council of Europe, Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine ETS No. 164, 1997; Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes CETS No. 203, 2008; United Nations

law, I include parliamentary debates, such as, parliamentary questions and responses from the Department of Health. Policy documents like the government's strategy on personalised medicine are also studied.[14]

Section 1 presents the core steps that Denmark has taken to introduce personalised medicine into healthcare. In Section 2, I demonstrate that self-determination expressed through informed consent does not underlie the current legislative landscape. Section 3 suggests that Danish healthcare could instead provide an example of solidarity-based personalised medicine, given the communitarian and trust-based nature of the Danish welfare state. To evaluate whether solidarity-based governance is applicable, I then analyse whether the legislation conforms to conditions suggested by Prainsack and Buyx, namely whether there is transparency, and whether legislation protects patient privacy and prohibits discrimination. Concluding that Danish legislation does not live up to the solidarity model, section 4 makes recommendations for how the legislation could be reformed. Finally, I reflect on the position of the minority patient in solidarity-based governance.

2. Personalised Medicine in Denmark – the Story so Far

Denmark has taken several key steps to introduce personalised medicine into clinical care, including pledging 100 million kroner (circa 13.4 million euro) in funding.[15] In 2015, the Danish Regions, together

Educational, Scientific and Cultural Organization, The Universal Declaration on the Human Genome and Human Rights, 1997. As the Genetic Testing Protocol is a specific legal instrument drafted by states, it is drawn on as best practice for identifying relevant rights. However, Denmark cannot be held in breach of its provisions as it has neither ratified nor signed the Protocol. Further, the Protocol is only applicable to treatment, not research.

14 The legislation establishing the Danish National Genome Centre is not a standalone Act, but amends the Health Act. Therefore, although the primary focus of this article is on the specific amendments, the Act is read as a whole.

15 10 million kroner was set aside in 2017, and 30 million a year in 2018–2020 (Finansministeriet, Finanslov for finansåret 2017: tekst og anmærkninger, p. 37). In 2018, following an application from the state, Novo Nordisk Foundation granted 990 million crowns (133 million euro) for establishing and operating the National Genome Centre.

with universities and a patient organisation, published an Action Plan for Personalised Medicine, with plans to offer genome sequencing to 100,000 Danes.[16] The Action Plan also called for the establishment of a national genome bank. Shortly after, in 2016, the Ministry of Health released its National Strategy for Personalised Medicine, making the case that this emerging health technology will benefit patients and society.[17] Personalised medicine, it is claimed, will lead to more targeted monitoring and prevention, more effective diagnosis and treatment, and better opportunities to improve patient health.[18] Like the Action Plan, the Strategy proposed the establishment of a National Genome Centre as a central pillar of personalised medicine.[19]

In September 2017, the government released a draft text of an amendment to the Danish Health Act which proposed to introduce legislative changes necessary to realise the national infrastructure proposed in the Strategy.[20] In response to criticisms, in February 2018, the government made changes and released the final text of the bill.[21] After tense debate, the amendments to the Health Act were adopted in July 2018. Further to powers delegated in the amendment, the Minister for Health issued secondary legislation in February 2019.[22]

Through the 2018 amendment, the government aims to provide the structures necessary for increased use of genetic data in treatment. The amendment establishes a National Genome Centre under the Ministry for Health with the purpose of developing a nationwide infrastructure for the retrieval and storage of genetic information, including a national

16 Danske Regioner, Handlingsplan for Personlig Medicin, 2015, p. 6. In Denmark, the regions are responsible for treatment and prevention. Sundhedsloven, § 3.

17 Strategy, see note 1.

18 Ibid., p. 6.

19 Ibid., p. 22–23.

20 Forslag til Loven om ændring af sundhedsloven Sundheds- og Ældreudvalget 2016–17 SUU Alm.del Bilag 470, 2017.

21 Folketinget, Forslag til Loven om ændring af sundhedsloven, L 146, 9 February 2018.

22 Sundheds-og Ældreministeriet, Høring over udkast til bekendtgørelser på Sundheds- og Ældreministeriets område – oprettelse af Nationalt Genom Center mv., 4 February 2019; BEK nr 360 af 04/04/2019, BEK nr 359 af 04/04/2019, BEK nr 361 af 04/04/2019, BEK nr 355 af 04/04/2019.

genome database for clinical and research use.[23] According to the legislature, using legislation to establish the National Genome Centre strengthens security and transparency when processing personal data.[24] The amendment also gives the Minister for Health the power to create rules requiring certain health institutions and healthcare workers, both public and private, to transfer genetic information derived from biological material, and health information, to the National Genome Centre.[25] This means that, from the 1st of July 2019, all dry genetic data derived from genome sequencing in healthcare must be transferred in the Genome Centre. Bekendtgørelse om Nationalt Genom Centers indsamling af genetiske oplysninger, nr 360, § 2, stk 1.

Despite near unanimous political support, the law-making process proved contentious. Both the 2017 draft bill and the 2018 bill drew sustained criticism in the media, with organisations like the Danish Institute for Human Rights concerned that the amendment could interfere with the right to private life.[26] While many organisations expressed support for the bill, several noted that certain provisions were unclear and exposed the individual to risks.[27] As a result of the criticisms, the government made several amendments, altering the originally intended scope of the bill. During the law-making process, 77 questions were submitted by

23 Lov om ændring af sundhedsloven, nr. 728 af 8. juni 2018 (Organiseringen i Sundheds- og Ældreministeriet, oprettelse af Nationalt Genomcenter m.v.), chapter 68.

24 Regeringen (Venstre, Liberal Alliance, Det Konservative Folkeparti) Socialdemokratiet Dansk Folkeparti Alternativet Radikale Venstre Socialistisk Folkeparti, Politisk aftale om Forslag til Lov om ændring af sundhedsloven (Organiseringen i Sundheds- og Ældreministeriet, oprettelse af Nationalt Genom Center m.v.), 22 Jan 2018.

25 Sundhedsloven, § 223a.

26 Lindblad, L., Kommende dna-center skaber bekymring: "Det opløser retten til privatliv", Politiken, 21 oct 2017; Beich, A., Birk Kristiansen, T, Pas på: Big Brother nærmer sig. State vil stjæle dine dna-oplysninger, Politiken, 2 Nov 2017, Straka,R., Stryhn Kjeldtoft, S., Politikere undrer sig: Rigspolitiet får adgang til dna-center, Politiken, 26 Feb 2018; Straka, R, Stryhn Kjeldtoft, S, Kritik: DNA-projekt er højrisikabelt for hele den danske befolkning, Politiken, 25 Feb 2018; Straka R, National genbank skal opdage fremtidens medicin, Politiken, 26 Feb 2018.

27 For example, Det Etiske Råd, Vedr. Det Etiske Råd besvarelse af høring over udkast til forslag til lov om ændring af sundhedsloven, 12 oktober 2017; Forbrugerrådet Tænk, høring over udkast til forslag til lov om ændring af sundhedsloven 16 oktober 2017.

organisations and politicians, concerning *inter alia* access to the data, self-determination and data security.[28]

The intense debate may be attributed to several factors. For one, the Bill was proposed while data security was under scrutiny, due to the entry into force of the European Union General Data Protection Regulation (GDPR), and because of a series of data breaches in Denmark. For instance, in 2015, the State Serum Institute sent a CD with unencrypted data relating to 5.3 million Danes' health to the Chinese Visa Application Centre, instead of the Danish Statistics Office.[29] Another basis for concern appears to be the perceived special nature of genetic data, known as genetic exceptionalism. Some feared that citizens' genomes would be sequenced without their consent, and that adequate safeguards were not in place. For instance, in 2018, it emerged that blood samples from 86,000 Danes were being stored in the USA to be used in a research project on psychiatric illnesses, without the Danish researchers securing the oversight required by law.[30]

The amendment, as adopted, reflects a form of genetic exceptionalism, whereby genetic data is governed differently to biological samples and other classes of health data. While the amendment increases patient self-determination when it comes to genetic data, it can be questioned whether informed consent is adequately protected in Danish health law, as discussed in the next section.

3. When Treatment becomes Research

While the amendment introduces several legislative changes, this article focuses on the reuse of biological samples without consent, which came to the fore during the debates on the National Genome Centre. In response, the government took certain steps to increase patients' self-determination. Yet, the amendment does not fully resolve the shortcomings that were previously in force and thereby continues to fall short of inter-

28 L 146, spørgsmål 1-77.

29 Data Tilsynet, 'Anbefalet brev afleveret til en forkert modtager'. 15-07-2016. Journalnummer: 2015-321-0307.

30 Stryhn Kjeldtoft, S, 86.000 danskeres dna opbevares ulovligt i USA, Politiken, 10 March 2018.

national norms. This is primarily because users of Danish healthcare can still become – what I term – "incidental research subjects", whereby the act of consenting to treatment can result in a patient's biological samples being sequenced for research. Below I explain the process by which this can occur and argue that the right to informed consent is not adequately safeguarded.

In clinical practice, biological samples are routinely gathered as part of diagnosis and treatment. In Denmark, the samples are often subsequently stored in local or national biobanks, and can be retrieved should the patient's treatment require.[31] In some cases, there is a system in place for informing patients of this process. For example, when parents consent to new-born screening for congenital diseases, such as *phenylketonuria* (PKU), they are given an information leaflet which explains that leftover samples are stored in the Neonatal Screening Bank (commonly called PKU Bank).[32] In contrast, when a patient has a biopsy performed at a hospital or a blood sample taken at a doctor's office, their sample is sometimes stored in a biobank without this being explained. Unknown to many is that these samples may also leave the confines of the clinic and move into the research world; in other words, samples are in some cases processed for purposes beyond patient treatment. The Danish Health Act allows for biological samples to be given to researchers without obtaining patient consent in connection with approved research projects.[33] This creates a parallel system to the usual requirement that researchers must obtain written informed consent before commencing research using biological samples.[34] Researchers apply to use patient samples in a range of research projects and, increasingly, perform genetic analyses on the samples, including whole genome sequencing.[35]

31 See further, Danish Council of Ethics, Research with health data and biological material in Denmark, 2015.

32 Statens Serum Institut, Til Forældrene: Blod Prøve fra Nyfødte, 13. udgave, København, 2017.

33 Sundhedsloven, § 32.

34 Bekendtgørelse af lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter (Komitéloven), nr 1083, 15 September 2017, § 3.

35 See further, Danish Council of Ethics, note 31; Nørgaard-Pedersen, B. & Hougaard, DM., Storage policies and use of the Danish Newborn Screening Biobank, Journal of Inherited Metabolic Disease, Vol. 30, Nr. 4, pp. 530–536, 2007.

Users of the Danish healthcare system can however, avoid becoming incidental research subjects. Persons over 15 years can register, online or in writing, in The Tissue Usage Register *(Vævsanvendelsesregisteret)*. Once registered, biological material gathered for treatment may *only* be used for the patient's treatment, and purposes connected to it.[36] The phrasing of the legislation is paradoxical: it asserts the patient's right to limit how her samples are used, albeit subject to an obligation to take steps to enjoy the entitlement. Otherwise, consent to research is assumed.[37] The 2018 Amendment expands this system as it also allows patients to opt out of research using their "dry" genetic data (not just their biological samples as before).[38]

During the debates on the 2018 amendment, following criticisms, the Ministry for Health sought to equate the process of giving informed consent to treatment to also consenting to contribute to research. The Ministry repeatedly claimed, in response to questions, that the legislation enshrines informed and full consent.[39] Yet, this model more accurately represents presumed consent, which does not conform to the internationally recognised elements of informed consent, in particular the right to information and freedom to consent.

First, in terms of information, patients are not routinely informed that their samples may be stored and re-used for research. Clearly, when a patient consents to treatment, they do not (also) give consent to future use for research purposes, where no efforts have been made to inform them of the possibility. Subsequent to powers delegated in the 2018 amendment, the Minister for Health has introduced secondary legislation requiring that consent to treatment involving genetic analysis must be given in writing. The consent form informs the patient that her data can be stored in the Genome Centre and that she must opt out to avoid

36 Sundhedsloven, § 29 (emphasis added). Connected purposes include quality control, developing methods, teaching healthcare workers and other routine functions with a direct connection with the treatment.

37 Bekendtgørelse om Vævsanvendelsesregisteret nr 966, 22 September 2004.

38 Sundhedsloven, § 29(4).

39 See for example, Sundheds- og Ældreudvalget 2017–18 L 146 endeligt svar på spørgsmål 1, p. 2.

re-use.[40] Yet, this consent form is only used if the patient is undergoing genetic analysis, meaning the non-information paradigm prevails for patients having other forms of treatment. Furthermore, while this is a step towards greater transparency, the information provided is limited compared to that given to persons enrolled in research projects; the treating health professional will not be able to tell the patient whether their data will be used, or in connection with which research projects, and which results the samples may yield.

Second, it is debatable whether the consent given in such situations is free. Several factors undermine the essence of freedom. When consenting to genetic analysis, patients must agree to their data being stored in the Genome Centre and can only opt-out of re-use. This runs contrary to a non-binding recommendation of the Council of Europe Committee of Ministers, which states that refusal to consent to storage of biological materials should not lead to discrimination regarding the right to medical care.[41] Furthermore, through the opt-out, the legislation presents "yes" as the default, while "no" is the exception. The patient remains obligated to act to avoid future use of her samples, which requires motivation. She is thereby nudged to consent, as the latter has been framed by the health-care system as the preferred "choice".[42] The reuse of biological samples for research may be desirable or justifiable in the interests of society, but that does not mean that presumed consent is tantamount to *free* consent.

Thus, despite the claims of the Ministry for Health, I conclude that patients do not give informed consent to re-use of biological samples in line with international standards. Instead, this patient group is more accurately categorised as incidental research subjects. At the same time, this does not automatically render the legislation illegitimate. For instance,

40 Bekendtgørelse om information og samtykke i forbindelse med behandling og ved videregivelse og indhentning af helbredsoplysninger m.v nr 359, 4 April 2019, § 2, stk 5; Nationalt Genom Center, Informeret samtykke til omfattende genetisk analyse som led i din behandling (2019).

41 Recommendation CM/Rec(2016)6 of the Committee of Ministers to member states on research on biological materials of human origin (Adopted by the Committee of Ministers on 11 May 2016 at the 1256th meeting of the Ministers' Deputies), Article 5.2.

42 See further, Asmussen, IH. & Ó Cathaoir, KE., Making Access to a Population of Bodies in the Name of Autonomy, European Journal of Health Law, Vol. 25, Nr. 5, pp. 555–572, 2018.

although different ethical issues apply (for one, the patient is deceased), presumed consent is used in organ donation in several countries.[43] Still, the current approach is problematic as the government seeks to rely on self-determination as an ethical basis. Therefore, in the next section, I explore whether the presumed consent model could be reframed as an act of solidarity, which justifies limiting self-determination.

4. A State of Solidarity

Solidarity is a timely principle to draw upon in light of a growing discourse on its role within health law and genetics.[44] Already more than a decade ago, Knoppers and Chadwick argued that, in genetics, individualism rooted in autonomy and privacy was giving way to communitarianism in the form of solidarity.[45] Although the Danish legislation was not enacted with express reliance on solidarity, could it be reconceptualised (and thereby legitimised) as a form of solidarity-based governance? As a welfare state with a high level of public trust in institutions, Denmark seems to offer appropriate conditions for solidarity-based personalised medicine.

Several factors suggest that the Danish healthcare system may be suited to solidarity-based governance. The country is a welfare state characterised by a communitarian ideology: the individual forms part of a larger collective.[46] Crucially, research suggests that citizens view public institutions as "trustworthy partners", heavily relied upon to per-

43 Rudge, CJ, Organ donation: opting in or opting out? Br J Gen Pract Vol. 68 (667), pp. 62–63, 2018.

44 Recourse to solidarity is increasing generally in public and academic discourse (Prainsack & Buyx, p. 6). In contrast, Rose suggests that increasing "personalization" may challenge solidarity, Rose, N., Personalized Medicine: Promises Problems and Perils of a New Paradigm for Healthcare, Procedia – Social and Behavioral Sciences Vol. 77, pp. 341–352, 2013, p. 350.

45 Knoppers, BM, Chadwick, R., Human genetic research: emerging trends in ethics, Nature Reviews Vol. 6, Nr. 1, pp. 75–9, 2005. See also, Chadwick, R., Berg, K., Solidarity and equity: new ethical frameworks for genetic databases, Nature, Vol. 2, Nr. 4, pp. 318–21, 2001.

46 Svendsen, MN., The Social Life of Genetic Knowledge: A Case-study of Choices and Dilemmas in Cancer Genetic Counselling in Denmark, Medical Anthropology Vol. 25, Nr. 2, pp. 139–170, 2006, p. 141.

form important social functions, including healthcare.[47] Social trust and trust in institutions is therefore high; corruption is low.[48] Furthermore, the Danish welfare model is grounded in universalism: generous social benefits are funded through taxation and are available to residents – not only citizens.[49] Finally, Denmark boasts an advanced technological infrastructure; all residents are registered on the central person register (CPR), which enables linking demographic data with health and education data.[50] Through the CPR, the 25.3 million samples from 5.7 million people currently found in the Danish Biobank Register, can be linked to disease codes and demographic details from registers.[51] Therefore, a unified health infrastructure that offers tangible social benefits, coupled with high levels of trust and reliance on public institutions, may create conditions that encourage and incentivise patients to contribute, for instance, biological samples to further the development of personalised medicine.

At the same time, the Danish welfare state model, and the healthcare system, is under increasing strain. Longer life expectancy and low birth rate contribute to an ageing population.[52] While immigration has historically been low in Denmark, globalisation and EU enlargement is shifting demographics, and fostering xenophobia. Rapid developments

47 Svendsen, MN., Navne, LE, Gjødsbøl, IM., Dam, MS., A life worth living: Temporality, care, and personhood in the Danish welfare state, American Ethnologist, Vol. 45, Nr. 1, pp. 20–3, 2018, p. 23.

48 Lind Haase Svendsen, G., Tinggaard Svendsen G., Graeff P., Explaining the Emergence of Social Trust: Denmark and Germany, Historical Social Research Vol. 37, No. 3 (141), Controversies around the Digital Humanities, pp. 351–367, 2012.

49 Hartlev, M., The raison d'etre of Nordic Health Law, in Rynning E. & Hartlev M., (Ed.) Nordic Health Law in a European Context – Welfare State Perspectives on Patients' Rights and Biomedicine, Martinus Nijhoff Publishers, 2011, p. 54. See further, Ministry of Health, Healthcare in Denmark – an Overview, Ministry of Health, 2017, available at https://www.sum.dk/English/~/media/Filer%20-%20Publikationer_i_pdf/2016/Healthcare-in-dk-16-dec/Healthcare-english-V16-dec.ashx.

50 Bekendtgørelse af lov om Det Centrale Personregister nr 646 2 June 2017 (CPR-Loven). The register stores information such as name, address, gender.

51 Danmarks Nationale Biobank, The Danish Biobank Register, www.danishnationalbiobank.com/danish-biobank-register (23 May 2019).

52 Møller Pedersen, K., Bech, M., Vrangbæk, K., The Danish Health Care System: An Analysis of Strengths, Weaknesses, Opportunities and Threats. Copenhagen Consensus Center. https://www.copenhagenconsensus.com/sites/default/files/ConsensusReportDanishHealth_final.pdf.

in technology, while promising, are expensive for a small welfare state to guarantee for all residents. In light of these pressures, the prospect of cost-effective healthcare technology is attractive.

In the coming sections, I analyse whether the Danish consent model could be justified as a form of solidarity-based governance, drawing on Prainsack and Buyx's model. Their approach to solidarity stipulates that the individual accepts some cost to assist others (not merely herself). In terms of cost, in the current example, the patient's sample is stored and potentially reused for research. The relevant similarity may be suffering from an illness or simply being a user of the publicly funded healthcare system. Therefore, the Danish legislation seems to fall within what Prainsack and Buyx classify as solidarity.

In their chapter on governing health databases, Prainsack and Buyx detail further conditions that should exist for a database to be suitable for solidarity-based governance: people should knowingly contribute, the database should create social value and offer appropriate incentives.[53] These conditions should ensure that the costs placed on the individual are reasonable and avoid individuals being "left alone when they suffer actual harm".[54] In this article, I assume that the data creates a social value as it does not *primarily* serve commercial interests.[55] Accordingly, in the next section, I evaluate whether the legislation in Denmark provides for transparency through ensuring patients are aware that they are contributing data for health-related research.[56] Following this discussion, I focus on whether the costs are acceptable, namely whether patients are adequately protected from discrimination and privacy violations.

4.1. In the Dark

According to Prainsack and Buyx, for governance to be driven by solidarity, the individual must *willingly* contribute to a common goal and thereby realise that they are accepting some costs, beyond their own

53 Prainsack & Buyx, note 11, p. 106.
54 Ibid., p. 170.
55 Ibid., p. 102–105.
56 Ibid., p. 102–103.

interests.[57] Those contributing to solidarity-based governance must be aware that they are doing so and know how their data will be used.[58] This requires "minimum levels of transparency" and veracity about what costs the patient may incur.[59] Prainsack and Buyx further posit that "data donors" should be treated as "information equals", which requires that individuals are supported "in making meaningful decisions".[60] In their discussion of presumed consent to organ donation, Prainsack and Buyx state that opt-ins only foster solidarity if "people are truly aware of consent being presumed."[61]

The Danish approach is immediately challenging in light of this requirement. For the Danish model to amount to solidarity-based governance, patients must be aware that presumed consent is enshrined in law, know that they are contributing to research, and know that they have the option to opt out.[62] Yet, the new information requirement included in the 2018 amendment only applies where the patient gives consent to a genetic analysis, meaning that patients who have biopsies or other samples taken will (as before) not be informed of the Register, even though approved research projects often carry out whole genome sequencing of samples.[63]

Furthermore, if solidarity requires willingness to contribute, the position of persons who do not have legal capacity to consent is also problematic. Firstly, in the case of children, until they reach age 15, parents or guardians consent to treatment, including genetic analysis, on their behalf.[64] Likewise, only parents or guardians can register minors/persons without capacity on the Tissue Usage Register.[65] The result is that by the time a child reaches 15 years and has legal capacity to opt-out, her genome may already have been sequenced because her parents have

57 Ibid., p. 104.
58 Ibid., p. 174.
59 Ibid., p. 103.
60 Ibid., p. 111.
61 Ibid., p. 164.
62 Ibid., p. 164.
63 Nørgaard-Pedersen, B. & Hougaard, DM., note 35.
64 Sundhedsloven, § 17(1).
65 Sundhedsloven, § 18.

consented to genetic analysis. Likewise, subject to safeguards discussed in section 3.3, a child's genome could be sequenced from samples stored in the PKU bank without the child's knowledge or consent, but based on the consent of their parents, given in the first (sometimes chaotic) days of life. This can run contrary to the spirit of Genetic Testing Protocol, which states that genetic testing must be deferred until the child has capacity to consent, unless delay would be detrimental for her health or well-being.[66]

Danish legislation also fails to adequately enshrine the rights of persons with disabilities. Provided a family member, guardian or an individual with power of attorney consents, genetic analysis may be carried out on a person who cannot consent. Similarly, samples can be reused for research unless the substituted decision maker opts out on the patient's behalf.[67] Contrary to Article 9 of the Biomedicine Convention, no provision is made under Danish law for the individual's wishes to be taken into account in this context, should she lose decision-making capacity in the future (although one's opt-out while competent under the Tissue Usage Registry would remain valid). This is not in keeping with the spirit of Article 12.5 of the Convention on the Rights of Persons with Disabilities, which requires that states take "appropriate and effective measures" to ensure that persons with disabilities have equal protection – a provision generally interpreted to include advance care directives.[68]

By including children and persons who cannot consent, the presumed consent model runs contrary to the solidarity approach suggested by Prainsack and Buyx. The current model potentially automatically enrols patients – who cannot opt out, and who are wholly reliant on others to do so – in research projects. All persons have rights to privacy and self-determination. Therefore, children and persons with disabilities should participate in decisions related to genetic sequencing and opting out. In reflection of this, Danish law requires that persons who cannot consent are informed and included in treatment discussions. However, the effectiveness of the provision is dampened by a paternalistic excep-

66 Genetic Testing Protocol, see note 9, Article 10.

67 Sundhedsloven, § 18.

68 UN General Assembly, Convention on the Rights of Persons with Disabilities, 13 December 2006, A/RES/61/106, Annex I.

tion, whereby persons who cannot consent should only be included in so far as inclusion does not harm them.[69]

Based on this analysis, the current legislation does not meet the transparency requirements of solidarity-based governance. Patients are inconsistently informed of the potential re-use of their biological samples and the ability to opt out. Furthermore, patients without capacity to consent are included in the opt-out system, even though they cannot willingly choose to participate. In section 4, I will consider whether these barriers to solidarity-based governance can be remedied.

4.2. Protection from Genetic Discrimination

Solidarity-based governance also requires that the state protects patients from harmful consequences. Genetic discrimination is of particular concern in personalised medicine given its potentially widespread implications in multiple contexts, from access to insurance to criminal law.[70] From a societal standpoint, genetic discrimination is undesirable for pragmatic reasons: fear of genetic discrimination could inhibit individuals from participating in research,[71] while patients may be discouraged from undergoing genetic sequencing for fear of negative implications for themselves and their families.[72] Genetic discrimination furthermore runs counter to international human rights law, namely, the prohibition of discrimination based on "other grounds".[73] This section assesses the extent to which Danish law protects patients from genetic discrimination.

69 Sundhedsloven, § 20.

70 Wong, SHY., et al., From Personalized Medicine to Personalized Justice: The Promises of Translational Pharmacogenomics in the Justice System, Pharmacogenomics Vol. 11, Nr. 6, pp. 731–7, 2010.

71 Feldman, EA., The Genetic Information Nondiscrimination Act (Gina): Public Policy and Medical Practice in the Age of Personalized Medicine, Journal of General Internal Medicine, Vol. 27, Nr. 6, pp. 743–6, 2012.

72 Bottinger, EP., Foundations, Promises and Uncertainties of Personalized Medicine, Mount Sinai Journal of Medicine: A Journal of Translational and Personalized Medicine, Vol. 74, Nr. 1, pp. 15–21, 2007.

73 See further, de Paor A., Genetics, Disability and the Law: Towards an EU Legal Framework, Cambridge Disability Law and Policy Series, Cambridge University Press, United Kingdom, 2017.

Danish law provides for important protections from genetic discrimination in the fields of insurance, pensions and employment. Firstly, legislation prohibits use of *predictive* genetic information (information that explains a person's genes, or risk of developing or incurring diseases) in insurance and pensions assessments.[74] An insurance company is only entitled to request, obtain or receive and use information that may clarify a person's *current* or previous state of health.[75] Additionally, since 2016, insurance companies cannot receive, obtain or request information relating to the health of others, including information about relatives' health.[76] The basis for the amendment was that families often lack complete information about their relatives' health. Further, information on familial risk is not a reliable prediction of future risk.[77] This provision is furthermore in line with the recommendation from the Council of Europe, which advises that family members' genetic tests should not be processed for insurance purposes.[78]

Likewise, an employer may not apply for, obtain, or receive and use health information for clarifying an employee's *risk* of developing diseases.[79] The employer should not seek information on familial health or initiate investigations with a view to determining whether an individual has a propensity for a genetic disease.[80] The employer may only request health information (including information from genetic analyses) for the purpose of clarifying whether the employee has a disease or has or had symptoms of a disease, where the disease will have a significant impact

74 Bekendtgørelse af lov om forsikringsaftaler, nr 1237, 12 Nov 2015, § 3; Lov om firmapensionskasser nr 1703, 27 December 2018, § 11.

75 Ibid.

76 Lov om ændring af lov om forsikringsaftaler og lov om tilsyn med firmapensionskasser Nr. 638, 8 June 2016 (Udvidelse af forbud mod indhentelse og anvendelse af visse helbredsmæssige oplysninger ved tegning m.v. af forsikringer og pensioner).

77 Betænkning afgivet af Retsudvalget den 19. maj 2016.

78 Recommendation CM/Rec (2016) 8 of the Committee of Ministers to the member States on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests (Adopted by the Committee of Ministers on 26 October 2016 at the 1269th meeting of the Ministers' Deputies), para. 17.

79 Lov om brug af helbredsoplysninger m.v. på arbejdsmarkedet, nr. 286, 24 april 1996, § 2(2).

80 Ibid., § 1(3).

on the employee's ability to carry out their work.[81] As de Paor notes, discrimination on grounds of genetic features may also be contrary to the prohibition of discrimination under the EU Charter, which should inform the interpretation of EU legislation, such as the Employment Equality Directive.[82]

The European legal landscape governing genetic discrimination is fragmented, with no standard for what adequate protection requires.[83] Danish patients enjoy certain protections from discrimination in insurance, employment and pensions, should it come to light that they bear a mutation that indicates a disease risk. These protections are important given the unreliable nature of some findings. Still, there can be implications where genetic sequencing shows an individual is *currently* suffering from a previously undiagnosed genetic disease. The boundaries between disease risk and disease diagnosis can be fluid. Patients may thereby be unsure as to what information they should report to insurers, while case assessors in insurance companies or in human resources may struggle to make systematic and accurate distinctions, leaving patients vulnerable to inconsistent decisions. Unless appealed, these interpretations go on behind closed doors, meaning that we know little about how the law is implemented in individual cases.

To address latent discrimination risks and boost patient autonomy, it may be desirable to provide impartial information on the potential insurance implications of undergoing genetic testing, or enrolling in research projects involving sequencing. Again, the incidental research subject is particularly vulnerable, as she is unaware of her assumed consent to research. So far there is no evidence of sequencing based on presumed consent leading to incidental findings of such significance that the researchers are ethically compelled to inform the research subject.[84] However, if, as predicted, we soon come to better understand the link between genetics and disease risk, there may be insurance implications

81 Ibid., § 2(2).

82 de Paor, see note 73, p. 252.

83 Ibid., p. 259.

84 The National Research Ethics Committee has set guidelines for when incidental findings should be reported. National Videnskabsetisk Komité, Vejledning om genomforskning, Copenhagen, 1 June 2018, section 5.2.

for incidental research subjects. These implications are another reason why patients must be better informed of their "donations". Additionally, more clarity is needed as to whether genetic discrimination occurs in other contexts, such as family law decisions, including adoption, and financial decisions, such as access to loans or mortgages.

4.3. Privacy

The principle of transparency further requires an appropriate level of foreseeability: the patient should know who will have access to her data and under what circumstances. Thus, legislation should limit the actors with access to the data according to clear, transparent grounds. In this section, I introduce the legal framework governing sharing of genetic information and explore under which circumstances genetic data can be shared with police.

While the government originally proposed a single, secure infrastructure for the storage of genetic data, it actually creates the opposite: a parallel system. Only dry data will be transferred to and stored in the National Genome Centre. Meanwhile, biological samples will continue to be stored in various biobanks around the country. Additionally, data gathered prior to the legislation entering into force cannot be transferred to the Genome Centre unless the patient consents. Biological samples will continue to be reused for research, separate to the data held in the Genome Centre. Therefore, the proposed simplified system can, if anything, be said to further complicate the legal landscape as different rules apply depending on where the data is stored.[85]

The Danish Data Protection Act, following the GDPR, limits the *purposes* for which personal and health data can be processed, while the Health Act also limits the actors who can access health data without patient consent.[86] For instance, electronic health data can be processed for several purposes without patient consent but only by authorised

85 For an analysis of the law governing research data, see Hartlev, M., Udvalgte love og regler for forskning med mennesker in Forskningsmetoder i folkesundhedsvidenskab (5. udgave) Eds. Signild Vallgårda og Anja Marie Bornø Jensen (forthcoming).

86 Section 6 (personal data) and 7 (sensitive personal data) of the Danish Data Protection Act (no. 502 of 23 May 2018).

health professionals.[87] Health data and biological samples gathered during treatment may be given to a *researcher* for use in a concrete research project, provided certain conditions are met.[88] In contrast, data held in the National Genome Centre may only be processed for two purposes: the treatment of the patient, or for statistical or scientific research of *significant societal importance*.[89]

Given these broad research exemptions, research ethics committees play an important role in protecting privacy. Where ethics approval is required, a research ethics committee must ensure that research projects do not violate the individual's right to physical and mental integrity, and right to private life.[90] The committee assesses the project's scientific standard, and carries out a risk assessment, including an assessment of whether the potential risks are acceptable in light of the possible reward.[91] Certain projects can be approved by regional committees, whereas the National Research Ethics Committee must approve projects relating to particularly complex areas, such as whole genome sequencing of samples from incidental research subjects.[92] This ensures consistency and continuity of decision-making. Historically, wet and dry data have been governed differently, with biological samples requiring research ethics approval, while access to health data from electronic patient records for research only required approval from the Danish Patient Safety Authority (*Styrelsen for Patientsikkerhed*).[93] However, since June 2018, the National Research Ethics Committee has required researchers to seek a new research ethics permission if they wish to conduct further research on dry genetic data generated from wet data, or if they wish to transmit the data to other researchers.[94] Currently, a legislative amendment is under consideration that will legally require researchers to gain ethics

87 Sundhedsloven, § 42d.

88 Sundhedsloven, § 32.

89 Sundhedsloven, § 223(b).

90 Komitéloven, § 20(4); Hartlev, M., Hybel, U., Bak Mortensen, Sundhed og Jura, Djøf, Denmark, 2017, p. 580.

91 Komitéloven, § 18(3).

92 Komitéloven § 15.

93 Sundhedsloven, § 32; The Patient Safety Authority only provides patient health data to research projects of "significant societal interest" (Sundhedsloven, § 46(2)).

94 See note 84, section 7.

approval to conduct research on sensitive biometric data, including dry genomic data.[95]

While the Health Act specifies the actors that may access general health data, the 2018 amendment did not originally specify who may access data held in the Genome Centre.[96] This led to concerns regarding which actors would be able to access genetic information stored in the Centre.[97] While it is clear from the above discussion that insurance and pensions companies and employers cannot access patient data without consent, one question was whether police could. During the debates on the 2018 amendment, the Minister for Health noted that, in extreme situations, special circumstances could provide grounds for granting a court order requiring the Genome Centre to give police access to genetic data held in the Centre.[98] This raised fears – could routine visits to a doctor's office result in patients unwittingly ending up in police databases without proper safeguards?

Based on limited existing case law, it seems that, at present, police will only be permitted to access data stored in the Genome Centre (or other biobanks) in strictly limited circumstances as, given the special nature of genetic information, the right to private life weighs heavily against societal interests. For instance, the Grand Chamber of the European Court of Human Rights has held that the retention of cell samples and DNA profiles interferes with the right to respect for private life *per se* given the "nature and amount of personal information".[99] The case underscores the European Court's recognition of the highly personal nature of genetic information, and the need for adequate safeguards for the individual's privacy.

The same considerations seem to apply at national level. In a case before the Danish courts, the police requested that *Statens Serum Institut*

95 Folketinget, Forslag til Lov om ændring af lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter og sundhedsloven (Styrkelse af borgernes tryghed og tillid til sundhedsforskning), L. 193, 28 Feb 2019.

96 See also, Kent Kristensen, Notat: Lov om Nationalt Genom Center, February 2018.

97 See, for example note 22.

98 Sundheds- og Ældreudvalget 2017–18 L 146, Spørgsmål 34, 28. februar 2018, available at http://www.ft.dk/samling/20171/lovforslag/L146/spm/34/1861444/index.htm.

99 *S and Marper v. the United Kingdom* [2008] ECHR 1581, para 73.

(SSI) locate and provide a sample held in the PKU bank in connection with a murder investigation.[100] On appeal, the Eastern High Court denied the application, finding that the provisions of civil process were not fulfilled. The Court held that the individual's sample could not be seized, as the action was not proportionate in light of the significance of the case and the harm that the measure may be expected to cause the individual. The decision focuses on the fact that the sample had been provided for screening of neonatal diseases. Samples gathered for neonatal screening could be retained for 50 years and indefinitely, if anonymized, while samples collected under the DNA register law may only be retained for 10 years.[101] If a sample from the PKU bank could be delivered to the police forty years after collection, but not under the DNA register law, this would be contrary to the DNA profile law and Article 8 ECHR.[102]

Both cases demonstrate that genetic information is currently stringently protected and authorities must meet a high burden to gain access. The cases illustrate the balancing of several public interests: the safe retention of health data, the resolution of violent crime and trust in healthcare. It thus seems that, for now, genetic data held in biobanks will only be provided to police in strictly limited situations that justify limiting the individual's rights under Article 8 ECHR.[103] However, as the European Court of Human Rights observed, technology will advance and we must be mindful of the potential for future misuse:

> … bearing in mind the rapid pace of developments in the field of genetics and information technology, the Court cannot discount the possibility that in the future the private-life interests bound up with genetic information may be

100 U.2017.1092Ø – TfK 2017.241.

101 Lov om oprettelse af et centralt dna-profilregister, nr. 434, 31 May 2000.

102 The central DNA register may only record information that is of police significance in connection with personal identification, not genetic information related to hereditary illness.

103 Samples have been transmitted from biobanks to the police in limited circumstances: to identify victims, and in one case to test against DNA found on a perpetrator, where no corpse was found. Det Etiske Råd, Et DNA-profil-register, som omfatter alle borgere i Danmark? Etiske overvejelser, 2006.

> adversely affected in novel ways or in a manner which cannot be anticipated with precision today.[104]

The debate around the amendment highlighted that, in some extreme situations, the police may be able to access the data held in the Genome Centre and other biobanks. Even if a patient opts-out of further use of her data for research, she must also ask the Genome Centre, and any other biobanks, to destroy the samples.[105] Otherwise, even if one has opted out, biological samples could potentially be transmitted to the police in certain instances. Yet, even if an individual takes all possible steps, the police may still be able to find a match if the data of close relatives, such as parents, siblings or children, is located. For instance, in the United States, suspects are increasingly identified through genetic data uploaded by relatives.[106] This only serves to highlight the interconnection between the individual and the collective, and the value of a solidarity approach, provided it offers adequate safeguards.

In line with the solidarity model, Danish legislation limits the actors and circumstances under which genetic data can be accessed. While researchers can be granted access to health and genetic data, this is increasingly subject to research ethics approval, which must safeguard the right to private life and ensure proportionate societal benefits. In the coming years, the use of genetic data in criminal investigations may take on increased significance as seen in other jurisdictions. While privacy is not absolute, it is vital that procedural safeguards are in place to ensure that any harms suffered by the individual are proportionate to the potential benefits to the collective.[107] For now, however, access to genetic data is strictly limited and will not be liberalised by the establishment of the National Genome Centre.

104 See note 99, para. 71.

105 Sundhedsloven, § 33, § 34.

106 Ram, N., Guerrini, CJ., McGuire, AL., Genealogy databases and the future of criminal investigation, Genetics and Privacy, Vol. 360, nr. 6393, pp. 1078–1079, 2018.

107 See further, Knoppers BM., & Thorogood, AM., Ethics and Big Data in Health, Current Opinion in Systems Biology, Vol. 4 pp. 53–57, 2017.

5. Evaluation of the Model

For solidarity to apply to the Danish presumed consent model, the following conditions must be met: transparency, veracity, and protection from harms associated with participation. The above discussion has highlighted several aspects that do not meet these requirements. Patients are inconsistently informed of the system of presumed consent, and potential uses of their data. Vulnerable groups, including children and persons without capacity to consent are included in the presumed consent model, and can only be excluded if a substituted decision-maker opts out on their behalf. In this section, I propose how the legislation could be improved to remedy these shortcomings.

Ultimately, the majority of the Danish population may wish to contribute to research, as some argue, but we cannot know this without more evidence. An opt-out system relies on a presumption that the majority, if asked, would wish to contribute, and that those who feel strongly enough will opt out. Currently, limited available statistics indicate that most Danish residents neither know of the Register nor that their samples can be processed for research without express consent. By 2011, only 186 individuals had registered on the opt-out registry.[108] During the debates on the Genome Centre, the Ministry of Health acknowledged the knowledge gap and committed to increasing awareness.[109] Yet, instead of remedying the lack of information, the amendment creates a parallel system of genetic exceptionalism.

The Ministry has regrettably not justified the presumed consent model. For example, the Danish Ethical Council recommends an ethical checklist, whereby health authorities should consider the evidence for the need for the type of intervention, review less restrictive alternatives and reflect on the positive effects vis-a-vis the negative impacts.[110] The role of scientific research, and the possible implications for individuals, are worthy of greater public acknowledgment and discussion, as recognised

108 Vaaben, L., Statens vævsregister stort set ukendt for borgerne, 1 April 2011, available at: https://www.etik.dk/etik/statens-v%C3%A6vsregister-stort-set-ukendt-borgerne.

109 See further, note 22.

110 Det Etiske Råd, Et venligt skub? p. 12–13, 2016.

in the UNESCO International Declaration on Human Genetic Data.[111] The government should therefore expand the new obligation to inform to include any patient providing a biological sample. This will increase patient awareness regarding the "incidental research subject" and the opportunity to take part in research.

The manner in which patients should be informed also requires reflection. If the majority of patients genuinely wish to opt-out, this should be respected. However, if the act of opting out is based on misunderstanding or incomplete information, it may not reflect a genuine choice. Nordfalk and Hoeyer have argued in relation to a separate opt-out to register-based research that, due to the inadequate phrasing, many did not understand the implications of opting out. Others had been registered by their parents as minors, of which they did not become aware when they reached adulthood.[112] The opt-out was removed after register-based research became unfeasible due to approximately 900,000 opt-outs. Therefore, the Ministry for Health must reflect on how best to increase knowledge for all patients. While the culture of trust in Denmark may help to justify presumed consent, it should not be exploited. Otherwise, the government may experience, as in the case of Iceland, that increased awareness will lead to a high level of opt outs, rendering presumed consent unfeasible.[113]

Perhaps technological solutions for greater patient involvement could offer an answer. For instance, through an app, patients could be provided with an opportunity to specify to which studies they wish to contribute, similar to the different options regarding organ donation. This could include offering examples of previous research projects that have used

111 States should endeavour to involve society at large in the decision-making process concerning broad policies for the collection, processing, use and storage of human genetic data and human proteomic data and the evaluation of their management, in particular in the case of population-based genetic studies. (Article 6(a), UNESCO International Declaration on Human Genetic Data (16 October 2003), SHS/BIO/04/1).

112 Nordfalk F., & Hoeyer K., The rise and fall of an opt-out system, Scandinavian Journal of Public Health, Vol. 1, p. 1–5, 2017.

113 For a detailed analysis of the Icelandic experience with presumed consent, see, Winickoff DE., Genome and Nation Iceland's Health Sector Database and its Legacy, Innovations: Technology, Governance, Globalization, Vol. 1, Issue 2, pp. 80–105, 2006.

data from incidental research subjects, and introducing patients to the work of Research Ethics Committees. The incidental research subject could be informed that her data has contributed to research through a brief abstract of the research project and its results. This could encourage ownership and awareness of societal contributions. It would also be in line with a Council of Europe Recommendation on research on biological materials of human origin, which calls on states to facilitate public access to general information on research collections and on conditions for obtaining, storage and use of biological materials for research purposes.[114] Minors should be informed when they come of age that their samples are being stored and reminded of the opportunity to opt-out.[115]

The rights of children and persons with potential difficulties to consent have not been given adequate attention. Following the solidarity model, samples from biobanks, like the PKU bank and data from the National Genome Centre, should not be reused for research until or unless the patient has capacity to willingly participate, i.e. they can legally opt-out. But is the opt-out truly the issue or is substituted consent the problem? In other words, if a parent/ guardian can consent to their child's genome being sequenced for treatment, is this any less problematic than a parent/guardian opting out on their behalf? Should substituted decision makers be permitted to make these decisions? I find it incoherent to conclude that parents/guardians cannot practice solidarity on another's behalf but can consent on another's behalf. I therefore consider the bigger question to be: under what circumstances should parents/guardians be empowered to consent to genetic sequencing on another's behalf? It should be noted that Danish legislation imposes stricter standards on research projects that use data from persons who cannot consent, for example, clear benefits must be offered for the research subject or the

114 Recommendation CM/Rec(2016)6 of the Committee of Ministers to Member States on research on biological materials of human origin (Adopted by the Committee of Ministers on 11 May 2016 at the 1256th meeting of the Ministers' Deputies), Article 8. See also, "individuals should be able to express preferences regarding the processing of their personal health data" (Recommendation of the OECD Council on Health Data Governance (The Next Generation of Health Reforms, OECD Health Ministerial Meeting, 17 January 2017)), recommendation 5(ii)(a)).

115 This would be in line with Recommendation CM/Rec(2016)6, Ibid., Article 12.5.

patient group.[116] The research ethics committee is as always bound to safeguard the child or individual's private life.

The opt-out model ensures that researchers can access data that is representative of the population, not only the smaller segments who enrol in research projects. If persons with potential difficulties to consent are excluded from research and personalised medicine, this may bring discriminatory results. In particular, personalised medicine for persons with psychiatric illnesses may be endangered, despite being a focus of the government's strategy.[117] Some research may only be possible with the participation of certain patient groups. Automatically excluding children and persons who cannot consent from research may therefore be contrary to children's best interests and patients' right to health.[118]

The ethical and legal position of persons who cannot consent needs discussion and analysis. It is problematic that neither the legislative nor political process has considered these ethical dilemmas. An analysis of the proportionality of including persons without capacity is needed, including data on the societal significance of these types of research projects and whether other models are feasible. Besides increased information provision for substituted decision makers, greater efforts should be made to foster participation of children and persons without capacity to consent. Other questions must be addressed, such as, under what circumstances genetic testing is appropriate for minors (including new-borns), and to what findings children (and their parents) are entitled.[119]

For most persons the immediate, direct burden of having one's biological samples and data stored for future research is minimal. The re-use of data without consent is less trivial, however. Danish legislation and policies on personalised medicine do not provide the necessary safeguards and thereby do not presently offer a suitable structure for solidarity-based governance.

116 Komitéloven, § 19.

117 Strategy, see note 1, p. 11.

118 UN General Assembly, Convention on the Rights of the Child, 20 November 1989, United Nations, Treaty Series, vol. 1577, p. 3.

119 See, for example, Ormond, KE., & Cho, MK., Translating personalized medicine using new genetic technologies in clinical practice: the ethical issues, Pers. Med., Vol. 11, Nr. 2, pp. 211–222, 2014.

6. Conclusion: Minorities and Solidarity

As more countries contemplate introducing personalised medicine, Denmark's experience can serve as guidance. Firstly, the law-making process underscores the need for consultation, clarity and communication. Secondly, the shortcomings of the legislation highlight the necessity of transparency, regardless of whether presumed or informed consent is enacted. Information while not a panacea – for one health literacy varies – is vital as long as self-determination remains a dominant norm in healthcare.[120] Thirdly, law is a tool for creating adequate safeguards, namely comprehensive protection of privacy and anti-discrimination legislation. Fourthly, the position of vulnerable groups, like children and persons with disabilities, requires consideration, including through public consultation. A more robust legislative and policy framework must be developed that addresses the pressing ethical and legal gaps.

Finally, it is worth reflecting on another question raised by Prainsack and Buyx, namely, solidarity with whom? Should solidarity-based personalised medicine only exist within the borders of the state, which is currently the focal point of healthcare, or should solidarity also contribute to shaping a more just world? There is some recognition that data sharing should facilitate better health outcomes for all. For example, the ethos of the GDPR – safe and rapid sharing of data within the EU – reflects this outlook.[121] International human rights law also encourages states to cooperate to realise the highest attainable standard of health beyond their own borders, while the UNESCO Declaration on the Human Genome calls for states to assist developing countries to carry out and benefit from research in genetics.[122] The International Declaration on Human Genetic Data states that benefits should be shared with society

120 Rothstein MA., Some Lingering Concerns about the Precision Medicine Initiative: Currents in Contemporary Bioethics, Journal of Law and Medical Ethics, Vol 44, Nr. 3, pp. 520–5, 2016, p. 522.

121 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ., Vol. L119, 4 May 2016, pp. 1–88, Article 1.

122 UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3, Article 2; UNESCO, Declaration on the Human Genome and Human Rights, Article 19.

as a whole and the international community.[123] Drawing on the right to enjoy the benefits of scientific progress, Knoppers and others argue for "a human rights approach to an international code of conduct for genomic and clinical data sharing".[124]

Yet, in Denmark, personalised medicine has been primarily framed as a national endeavour. Although the Action Plan and Strategy note the importance of international cooperation, the parliamentary debates of the 2018 amendment emphasise that personalised medicine is for the benefit of *Danes*. The debates reflect fears of genomic data being sent abroad,[125] with the National Genome Centre framed as an antidote: a national infrastructure that avoids biological material and personal data being sent outside of Denmark.[126] This reflects an inward-looking worldview: Denmark as safe, while abroad as dangerous.

Meanwhile, the current government is openly hostile towards non-Western immigrants, introducing laws and policies aimed at limiting their access to public benefits.[127] Danish homogeny is in fact often lauded as a resource that should be harnessed.[128] These aspects may leave

123 International Declaration, note 111, Article 19(a).

124 Knoppers, B., A human rights approach to an international code of conduct for genomic and clinical data sharing, Human Genetics, Vol. 133, pp. 895–903, 2014.

125 One of the questions asked during the debate was whether Danes' genetic information will be sent abroad without being informed, and if so, whether the data processors abroad would be inspected. (Sundheds- og Ældreudvalget 2017–18, L 146 endeligt svar på spørgsmål 1, 13 April 2018).

126 Sundheds- og Ældreudvalget 2017–18 L 146 endeligt svar på spørgsmål 60, 13 April 2018.

127 In the 2015 general election, the Danish People's Party won 37 out of 179 seats (up 15 from 2011). The party is opposed to immigration: "Denmark is not an immigration country… we will not accept a multiethnic transformation… Denmark is the Danes' land". See, Danish People's Party, Principprogram, available at: https://danskfolkeparti.dk/politik/principprogram/ See for example, Sundhedsloven, § 50(1) [Since 2018, persons living in Denmark for over 3 years must pay for interpretation in healthcare]; Regeringen, Ét Danmark uden parallelsamfund – Ingen ghettoer i 2030, marts 2018. [In 2018 the government launched the so-called "ghettoplan", which recommends higher penalties for crimes committed in designated locations, obligatory day-care for children aged 1 living in certain locations].

128 See for example, Innovationsfonden, Sundhed: Investeringsstrategi for Innovationsfonden 2016–2018. "Danmarks CPR-registrering og homogene befolkning kombineret med høj faglighed i sundhedsvæsenet og patienternes tillid giver unikke muligheder for at kunne følge forebyggelse og behandling af individuelle patienter gennem hele livet." (p. 6).

minority ethnic groups questioning whether they are only to contribute, but not benefit from personalised medicine. The question of how residents and citizens who diverge from the infamous "homogeneity" of Danish society will be included and excluded from the government's ambitions for personalised medicine is yet to be addressed.[129] But without legal certainty and adequate protections, minorities may decide against participation. This is problematic for a universal healthcare system and may increase already existing health disparities.[130]

129 Persons from non-Danish backgrounds would not fit within the Danish Reference Genome, which has been developed for use in the Danish healthcare system. Maretty, L., Sequencing and de novo assembly of 150 genomes from Denmark as a population reference, Nature Vol. 548, pp. 87–91, 2017.

130 Most personalized medicine studies focus on populations of European descent, see, Brothers and Rothstein, see note 5, p. 46.